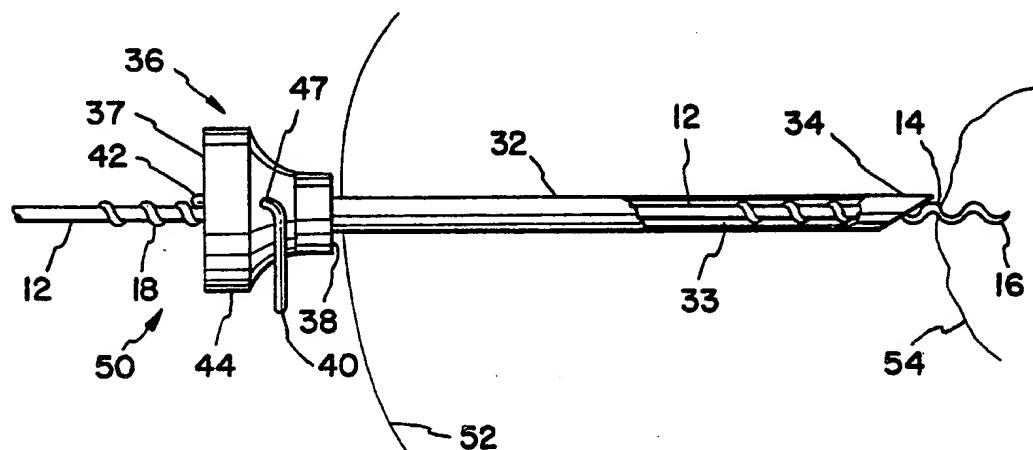




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :  A61B 10/00		A1	(11) International Publication Number: <b>WO 90/15576</b>  (43) International Publication Date: 27 December 1990 (27.12.90)
(21) International Application Number: PCT/US90/03244	(22) International Filing Date: 7 June 1990 (07.06.90)	(74) Agent: SCOTT, Anthony, C.; Scully, Scott, Murphy & Presser, 400 Garden City Plaza, Garden City, NY 11530 (US).	
(30) Priority data: 367,405 15 June 1989 (15.06.89) US	(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent)*, DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), SE (European patent).		
(71) Applicant: RESEARCH CORPORATION TECHNOLOGIES, INC. [US/US]; 6840 East Broadway Boulevard, Tucson, AZ 85710 (US).	(72) Inventors: RANK, William, R. ; 600 Deerfield Road, Apt. #204, Gretna, LA 70053 (US). NICHOLS, Ronald, Lee ; 1521 7th Street, New Orleans, LA 70115 (US). SCHOPENBERGER, Stephanie, G. ; 1812 Palmer Avenue, New Orleans, LA 70118 (US).	Published <i>With international search report.</i>	

## (54) Title: LESION LOCALIZATION DEVICE AND METHOD OF USING



## (57) Abstract

A lesion localization marking wire (10) and needle assembly (30) for marking non-palpable lesions within the body. A marking device (10) having a helically wound coil of wire (14) attached to an end of the shaft (12) which is insertable into the body through a needle or cannula (30) for rotatably anchoring the marking device (10) into a lesion or tumor (54) is provided. The needle or cannula (30) is inserted into the body with the marking device (10) positioned therein so that when the cannula is positioned proximate to a lesion (54) the shaft (12) of the marker is rotated to advance the marker (10) into the lesion to mark it for subsequent surgical procedures. A second helical wire (18) may be provided on the shaft (12) which cooperates with a wire guide device (40) attached to the needle (30) to enable the physician to determine the depth of the marking device (10) as it anchors into the lesion (54). In particular, the device is provided for marking for biopsy lesion of the breast.

## DESIGNATIONS OF "DE"

Until further notice, any designation of "DE" in any international application whose international filing date is prior to October 3, 1990, shall have effect in the territory of the Federal Republic of Germany with the exception of the territory of the former German Democratic Republic.

### FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Monaco
AU	Australia	FI	Finland	MG	Madagascar
BB	Barbados	FR	France	ML	Mali
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Fasso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GR	Greece	NL	Netherlands
BJ	Benin	HU	Hungary	NO	Norway
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	SD	Sudan
CF	Central African Republic	KP	Democratic People's Republic of Korea	SE	Sweden
CG	Congo	KR	Republic of Korea	SN	Senegal
CH	Switzerland	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
DE	Germany, Federal Republic of	LU	Luxembourg	TG	Togo
DK	Denmark			US	United States of America

- 1 -

1

LESION LOCALIZATION DEVICE AND METHOD OF USING

5

The present invention relates to lesion localization needles and devices, for use in localizing or marking non-palpable lesions and tumors within the body, and more particularly, the present invention relates to a needle assembly which includes a wire marker having a helically wound wire tip for rotatably anchoring a marker to a lesion within a human breast.

Localization or marking of lesions within the body, such as non-palpable lesions discovered within the body, and devices such as needles and wires for marking these lesions, 15 are well known in the art. The devices generally comprise a hypodermic needle or cannula which is inserted into the body under local anesthesia to a position adjacent and in contact with the lesion. The wire marker is then passed through the cannula and is anchored into the lesion so that the lesion is 20 marked for subsequent surgical procedures such as excision or biopsy. After marking the lesion with the wire marker, the cannula is usually removed from the body, leaving the wire in place and extending from the body. However, these markers tend to dislodge and migrate during transport of the patient 25 for the surgical biopsy procedure.

Increasingly, ultrasonic imaging is being used as a preferred ancillary or adjunctive imaging method to evaluate breast masses which may be associated with positive or negative mammographic findings. Currently available 30 localization and marking devices image poorly, if at all, ultrasonically, making it difficult to accurately pinpoint

-2-

the tip of the localization wire with respect to the lesion.

1 Consequently, a subsequent surgical biopsy procedure may result in an inaccurate incision causing unnecessary tissue damage, and may necessitate a second surgical procedure to properly biopsy the lesion, causing the patient unnecessary pain, suffering, and expense.

In the prior art, several types of lesion localization devices and lesion markers are disclosed. Currently, the method of detecting and performing a biopsy on a non-palpable occult lesion within the body, such as non-palpable breast lesions, has been to radiologically or ultrasonically locate the lesion and to mark the lesion using a localization needle assembly, prior to a biopsy procedure. These needle assemblies generally comprise a hypodermic needle or cannula which is inserted into the body to an area adjacent to and in contact with the lesion. A marking wire is then inserted through the cannula into the lesion and anchored in place so that the cannula may be removed.

10 Ultrasonic imaging is increasingly being used as the preferred method of detection and evaluation of lesions and masses within the body due to its accuracy, and in view of the fact that the patient is not exposed to potentially harmful radiation for extended periods of time. The prior art marking devices generally image very poorly ultrasonically, as the tip of the previous marker shows up as a small, hard to locate dot or spot on the viewing screen. Depth perception is very limited, and consequently, accurate, reliable placement of the previous marking device is not guaranteed.

15 20 25 30 35 Nicholson, et al., U.S. Patent No. 4,616,656, discloses a probe wire and sheath assembly in which the wire has a J-type memory hook for marking lesions. The wire probe has a soft flexibility so that when it is enclosed within the sheath it has a straight configuration. The sheath, or needle, is inserted into the body, for instance into the

-3-

1 breast of a female patient, and positioned proximate to a  
lesion. The wire probe is then pushed further into the  
lesion so that the memory hook is reformed and anchors itself  
within the lesion. The sheath is then removed leaving the  
hook embedded in the lesion as a marker.

5 10 15 A similar device is disclosed in Hawkins, Jr., U.S.  
Patent No. 4,230,123. Hawkins, Jr. discloses a needle sheath  
assembly which consists of a small gauge needle in which a  
stylus or wire is positioned within a cannula. A shorter  
outer sheath is slidably located over the cannula which is  
removable after insertion of the needle into the patient's  
body. The wire has a J-type hook which is passed through the  
cannula to stabilize the tip of the cannula during biopsy.

20 25 30 35 Nicholson, et al. and Hawkins, Jr. are subject to  
several disadvantages which effect the accuracy and  
performance of the device. Devices such as those disclosed  
in these references image very poorly and are inconsistently  
visualized ultrasonically, and consequently may not be  
accurately placed. Furthermore, in procedures involving  
lesions of the breast, the breast is compressed during the  
mammographic localization procedure so that after the needle  
is in place and compression discontinued, the needle marker  
may inadvertently dislodge or migrate to a different position  
than that set during the localization procedure. The needle  
may also deflect away from the lesion, or if the strength and  
resiliency of the wire is less than that required to  
penetrate the lesion, the hook may not reform, allowing the  
marker to migrate or dislodge. This can result in damaging  
the tissues of the breast, as well as an inaccurate surgical  
incision during the biopsy procedure, usually requiring a  
second surgical procedure to properly biopsy the lesion,  
causing the patient unnecessary pain, suffering and expense.  
Devices of this type also generally require that the breast  
be stabilized during transport of the patient from the  
radiology section of a hospital to the surgical section for  
the biopsy procedure in order to prevent dislodgement of the  
marker.

-4-

1        Simon, U.S. Patent No. 4,790,329, discloses a  
1        biopsy localization device having a sheath or cannula through  
1        which a barbed rod passes. The cannula is provided with  
1        an open side port through which the barb extends upon  
5        positioning within a lesion. In use, the barb is compressed  
5        within the lumen of the cannula and the pointed end of the  
5        rod extends from the cannula. As the device penetrates the  
5        patient's body, and into a lesion, the rod is rotated 180° so  
10        that the end of the barb may pass through the open side port  
10        of the cannula. The rod is then drawn back so that barb and  
10        cannula anchor into the lesion to prevent removal. While the  
10        device is relocatable, such as by drawing back the cannula to  
10        enclose the barbed rod after anchoring, it is apparent that  
10        some tissue damage will result due to the barb puncturing  
15        the tissue once it is anchored. In addition, the cannula  
15        remains in place while the lesion is marked by the barb,  
15        which results in excessive weight applied to the tissue. The  
15        entire device must be stabilized in order to prevent tearing  
15        of tissue and dislodgement of the marker. As related to  
20        breast lesions, as discussed above, compression of the breast  
20        during the procedure provides accurate anchoring of the barb;  
20        however, during transport of the patient, the additional  
20        weight of the cannula as well as the barbed rod will require  
20        stabilization of the breast to prevent migration and  
25        dislodgement of the device. A similar device, facing the  
25        same disadvantages, is disclosed in Hawkins, et al., U.S.  
25        Patent No. 4,799,495.

30        An additional type of prior art lesion  
30        localization and biopsy device is commonly referred to as the  
30        "Nordenstrom Screw Diagnostic Instrument", which was  
30        developed by Bjorn Nordenstrom (Radiology, November 1975,  
30        Volume 117, Page 474). The Nordenstrom screw is generally a  
30        biopsy device and not a lesion localization and marking

-5-

1 device. A cannula is provided which is inserted into the  
1 body, having a screw-tipped rod within the lumen of the  
cannula. When the cannula is positioned proximate a lesion,  
the rod is rotated to screw the tip into the lesion. The  
screw tip is integral with the rod itself, and is a finely  
5 machined device in which the screw threads define grooves  
which taper to the tip of the device. After the screw tip is  
rotated into the lesion, the cannula is then rotated in an  
opposite direction using slight forward pressure to a  
position over the screw threads. Tissue from the lesion is  
10 captured in the grooves of the screw tip and the entire  
device is withdrawn so that the tissue may be examined. The  
Nordenstrom screw device, as stated above, is not a marking  
device, but instead allows the physician to immediately  
15 biopsy the lesion in question.

15 An additional marking device using a screw tip is  
disclosed in Hawkins, et al., U.S. Patent No. 4,799,495. In  
this device, the cannula may be provided with a tapering  
screw tip to anchor the cannula in the tissue while the  
needle marker penetrates the lesion. The cannula and wire  
20 are used to mark the lesion, and Hawkins et al. also  
discloses the use of the cannula alone for marking the  
lesion. Furthermore, Hawkins et al. discusses a helical  
screw needle marker, similar to the Nordenstrom screw device,  
which may be inserted through the cannula to mark the lesion.  
25 However, the tapering screw tip of Hawkins et al. is a finely  
machined device which is quite expensive to manufacture, and  
which also is subject to the disadvantage that the tapered  
end may result in the loosening or "backing off" of the screw  
tip which will dislodge the marker during transport of the  
30 patient, or upon discontinuation of compression of the breast  
during the marking procedure. Furthermore, the precise  
machining of the tip of this device, and in particular a

-6-

1 hollow screw-tipped cannula, would be a difficult and very  
5 expensive procedure from a manufacturing standpoint, and  
would necessitate that the device be reusable due to these  
cost considerations. In view of this, and in light of  
5 current health risks and concerns for patient safety as  
related to blood products and invasive surgical procedures,  
sterilization procedures would be required prior to and after  
each use, thereby making the procedure more elaborate and  
expensive than normally necessary.

10 The novel, disposable lesion localization and  
marking device of the present invention obviates the problems  
associated with the prior art lesion localization devices by  
providing an inexpensive, simple to manufacture lesion  
marking device having a helically wound marking wire attached  
15 to a wire shaft which passes through a hypodermic needle  
comprising a cannula. The helically wound marking wire  
extends concentrically outward from the shaft and maintains a  
substantially uniform diameter so that once the wire is  
rotated or screwed into a lesion, it remains anchored in the  
20 tissue without the possibility of backing off and dislodging.

25 In a preferred embodiment, a second helically wound  
wire is provided on the shaft remote from the first helically  
wound wire at the tip which, in conjunction with a wire guide  
provided on a gripping knob of the cannula, assists in the  
forward advancement of the shaft so that excessive forward  
pressure is not required, and the second helix also acts as a  
depth guide to provide an accurate indication of the depth to  
which the first helix is embedded in a lesion. The helically  
wound wires are secured to the shaft by means such as  
30 soldering, or may be wound as part of the shaft itself, so  
that the entire device is simple to manufacture and  
relatively inexpensive, thereby making the device disposable  
following the biopsy procedure.

1        The present invention eliminates or substantially ameliorates the disadvantages encountered in the prior art through the provision of a lesion localization and marking device having a helically wound wire tip attached to a shaft 5 which is inserted within the lumen of a cannula into the body and then rotated into a lesion to anchor the marker within the lesion tissue. The device is simple to manufacture and inexpensive thereby making it a disposable unit, which may be packaged in a sterile packaging unit for one time use.

10      The lesion localization and marking device of the present invention consists of a marker having a shaft constructed of stainless steel or other biocompatible material which has secured to its distal end, or formed integrally thereon, a stainless steel wire which is helically wound about the end of the shaft. The helically wound wire extends outwardly in a concentric manner from the end of the shaft and overhangs the shaft a predetermined distance. The end of the helix is sharpened to facilitate insertion into a lesion within the body. The helical wire is secured to the shaft by conventional means such as soldering.

15      The marking device, when used in conjunction with the needle assembly of the present invention, may be provided with a second helically wound wire which is secured to the shaft of the marker remote from the end having the first helically wound wire. The second helically wound wire is secured to the shaft by soldering, or integrally formed as part of the shaft, and is dimensioned to have the same number of turns per centimeter as the first helically wound wire, thus having the same pitch or angle for each turn of coil.

20      The marking device is positioned within a hypodermic needle or cannula which essentially comprises a stainless steel tube having a cutting edge at one end and a thermoplastic gripping

1 knob at its other end. The gripping knob has a hole bored  
1 through the center which preferably aligns with the lumen of  
the cannula, and a second hole is bored through the knob  
parallel to the first hole and offset from the center of the  
5 lumen. Through the second hole is positioned a wire guide  
which is bent perpendicular to the hole and placed to  
partially cover the first hole, leaving an opening which is  
substantially equal to the diameter of the shaft of the wire  
marker plus the diameter of the wire which forms the helix.

10 In use, the needle assembly is inserted into the  
body, such as into the breast of a female patient, until the  
tip of the cannula is proximate to a lesion which has been  
discovered during a mammographic or ultrasonic imaging  
procedure. The marking device is positioned within the  
cannula so that the sharpened tip of the first helical wire  
15 is adjacent to the cutting edge of the cannula, and the  
second helical wire is positioned a predetermined distance  
such that the end of the second helical wire closest to the  
first helical wire is adjacent to and engages the wire guide  
of the thermoplastic knob of the cannula. As the marking  
20 device is rotated, the second helical wire is guided along  
the wire guide so as to stabilize the shaft while drawing the  
marker into the cannula due to the interaction of the second  
helix and the wire guide during rotation, and the first  
25 helical wire is rotated into the lesion. The wire guide  
assists the forward advancement of the marker during  
rotation.

30 The length of the second helical wire is identical  
to the length of the first helical wire from the end of the  
shaft to the sharpened tip, and both helical wires have an  
identical number of turns per centimeter. As the first  
helical wire is embedded into the lesion, the physician can  
accurately gauge the depth to which the first wire enters the  
lesion by the distance the second helical wire extends

-9-

1 outwardly from the gripping knob of the cannula. When the  
second helical wire is fully rotated within the cannula the  
physician will know that the first wire is fully extended  
outside the cannula and is in position with respect to the  
5 lesion. The cannula is then removed from the body leaving  
the marking device in place.

As ultrasonic imaging is increasingly being used as  
the preferred method of evaluation of breast lesions in  
localization procedures, it is very important the the marker  
10 used in the localization procedure provide consistent  
visualization and clean imaging with a recognizable acoustic  
pattern. Prior art markers do not provide adequate  
ultrasonic imaging and consequently do not contribute to  
accurate localization of a lesion. The present invention,  
15 however, due to the helical tip, provides excellent imaging  
characteristics compared to prior art markers, such that each  
turn of the helix images distinctly, as opposed to the single  
spot or dot appearing from the prior art markers. As a  
result, the present marker provides an unambiguous ultrasonic  
20 image allowing for accurate marking of the discovered lesion  
under the same conditions as mammography, thus reducing the  
patient's exposure to X-rays as well as decreasing the number  
of repositions required to accurately mark the lesion.

The present invention relates to a needle assembly  
25 for localization of lesions within the body, including a needle  
cannula, said cannula having a cutting edge at a first end;  
and a marking device positioned within said cannula and  
including a shaft, said marking device being characterized  
by a wire helically wound at one end of said shaft and  
30 extending beyond said end a predetermined distance in a  
helical coil, and having a sharpened tip, said marking device  
being axially slidable and rotatable within said cannula.

The present invention further relates to a marking  
device for use in combination with a needle assembly for  
35 marking lesions within the body characterized  
by a shaft; a first helically

1 coiled wire secured to and wound about a first end of  
said shaft, said first wire extending concentrically  
outwardly from said first end and away from said shaft  
a predetermined length and terminating in a sharpened  
5 tip; and a second helically coiled wire secured to and  
wound about said shaft a distance from said first helically  
coiled wire, said second wire having a length equal to  
said predetermined length that said first wire extends  
from said shaft; wherein said first and second helically  
10 coiled wires are wound an equal number of turns of  
between 6 and 15 turns per centimeter.

The present invention also relates to a method  
for marking non-palpable lesions within the body, charac-  
terized by puncturing the skin to enter the body with a  
15 marking needle assembly, said needle assembly including  
a cannula having a lumen, a cutting edge at one end of said  
cannula and a gripping means on said cannula, said needle  
assembly further including a marking device positioned within  
said lumen, said marking device having a helical wire  
20 helically wound at one end a predetermined distance in a  
helical coil, and having a sharpened tip; said marking device  
being axially slidable and rotatable within said cannula;  
tracking said needle assembly inside said body; advancing  
said needle assembly to a point within proximity to a lesion  
25 within said body; rotating said marking device within said  
cannula to advance said marking device; determining the  
distance said marking device travels by the distance said  
marking device is advanced into said cannula; ceasing rota-  
tion of said marking device when said marking device is  
30 positioned within a determined proximal distance of said  
lesion; and removing said cannula from said body; wherein  
said marking device remains in position with respect to said  
lesion to mark said lesion for subsequent medical procedures.

1 The present invention will become more readily  
apparent and may be understood by referring to the  
following detailed description of the lesion localization  
and marking device having a helically wound wire tip,  
5 taken in conjunction with the accompanying drawings;  
in which:

Figure 1 illustrates a side elevational view  
of a marking device pursuant to the present invention;

10 Figure 2 illustrates a side elevational view  
of a hypodermic needle or cannula pursuant to the  
present invention;

15 Figure 3a illustrates an elevational end view of  
the gripping knob of the hypodermic needle of Figure 2 along  
lines 3a-3a;

Figure 3b illustrates an elevational end view of  
the cannula of the hypodermic needle of Figure 2 along lines  
3b-3b;

20 Figure 4 illustrates a perspective, partially  
sectional view of the lesion localization needle assembly  
pursuant to the present invention after insertion into the  
body but prior to marking a lesion;

25 Figure 5 illustrates a perspective, partially  
sectional view of the needle assembly of Figure 4 during  
rotation of the marking device within the cannula and into a  
lesion;

Figure 6 illustrates the needle assembly of Figure  
4 after rotation of the marking device into the cannula with  
the wire marker being fully embedded within a lesion;

30 Figure 7 illustrates a side elevational view of an  
alternate embodiment of a marking device pursuant to the  
present invention; and

35 Figure 8 illustrates a side elevational view of an  
alternate embodiment of a needle or cannula pursuant to the  
present invention.

1 Referring now in specific detail to the drawings, in which identical reference numerals identify similar or identical elements throughout the several views, Figure 1 shows marking device 10 according to the present invention.

5 Marking device 10 is constructed of a biocompatible material, and is preferably constructed of stainless steel, although many metal alloys such as aluminum alloy, titanium alloy, ferrous alloy, and the like, as well as materials such as plastic and ceramic, may be employed. Marking device 10

10 essentially consists of a shaft 12 which is preferably type 18-8 stainless steel having a thickness of between 0.011 and 0.20 inches diameter, and is preferably 0.016 inches diameter. Marking device 10 is provided at one end with helical marking wire 14 which is helically wound about the

15 end of shaft 12 and secured to the shaft as illustrated at 20. Preferably, helical marking wire 14 is constructed of the same material as shaft 12, and is secured to the shaft by soldering, preferably of a 98% tin and 2% silver solder.

20 Helical marking wire 14 is wound about shaft 12 and extends outwardly away from the shaft to terminate in a sharpened tip 16. The diameter of the coil formed by helix 14 remains constant along its length. Helix 14 extends from the end of shaft 12 a distance of between 0.5 centimeters and 2 centimeters, and preferably extends 1 centimeter from the end.

25 of shaft 12. The pitch of the coil is determined by the number of turns per centimeter, which along with the length of helix 14, is dependent upon the application for which the marker is to be used. Different tissues within the body have different degrees of strength and resiliency, some requiring more force to anchor the marker 10 in place, and thus some tissues require a device having more turns per centimeter than other tissues. Accordingly, helix 14 generally is provided with between 6 and 15 turns per centimeter, and preferably it is provided with 8 turns per centimeter for

30 marking breast lesions.

35

1 Separated a distance "d" along shaft 12 from  
helical marking wire 14 is helical guide wire 18 which is  
also wound about shaft 12. Helix 18 is constructed of the  
same material as helix 14 and shaft 12, and helical wires 14  
5 and 18 are the same gauge wire, preferably having a diameter  
of between 0.009 and 0.015 inches (0.02 and 0.04 cm). The  
preferred diameter for helical wires 14 and 18 is 0.011  
inches (0.027 cm) for marking breast lesions. Helix 18 is  
10 secured to shaft 12 in a manner similar to helix 14. Helix  
18 is of the same length as the length that helix 14 extends  
from the end of shaft 12 to sharpened tip 16, and also has  
the identical amount of turns per centimeter as helix 14, and  
thus the same pitch to the coil formed by helix 18.

15 Distance "d" is dependent upon the length of the  
hypodermic needle or cannula with which marking device 10 is  
to be used. This will be described in greater detail below.

20 As can be seen in Figure 2, hypodermic needle 30  
comprises a cannula 32 having a sharpened cutting tip 34 and  
a gripping knob 36. Cannula 32, like marking device 10, is  
constructed of biocompatible material, and is preferably  
stainless steel. In a preferred embodiment, the cannula is  
18-gauge thin wall stainless steel type 504, and has a length  
from tip 34 to knob end 36 of between 3 and 15 centimeters,  
25 depending upon the type and location of the lesion to be  
marked. Knob 36 is preferably constructed of thermoplastic  
material such as nylon and is secured to cannula 32 at end  
38 by conventional means such as epoxy, adhesives, and the  
like. Knob 36 may have a ridged gripping surface 44 which  
30 aids the physician in handling the needle 30. Cannula 32 is  
of course hollow and defines a lumen 33, as best seen in  
Figure 3B.

1                   Gripping knob 36 has a hole 46 bored through the  
knob, which in the preferred embodiment aligns with lumen 33  
of cannula 32 so that the cannula can extend through the hole  
to face 37 of knob 36. In addition to hole 46, a second hole  
5                   47 is bored through knob 36, which is offset and parallel to  
hole 46. A wire guide 40 passes through hole 47 and may be  
secured within the hole by conventional means such as epoxy,  
adhesives, and the like. Wire guide 40 passes through hole  
47 and is bent at 41 along face 37 of knob 36 to form guide  
10                  bar 42. Wire guide 40 may also loosely and pivotably rest  
within hole 47 so that guide bar 42 may be moved into and out  
of engagement with shaft 12 of marker 10. As seen in Figure  
3a, guide bar 42 partially covers hole 46 in knob 36 so as to  
reduce the opening of hole 46. The reason for this will be  
15                  explained in greater detail below.

Figures 4, 5 and 6 show needle and marker assembly  
50 in various positions during use of assembly 50 in marking  
a lesion within the body. Assembly 50 comprises marking  
device 10 as shown in Figure 1 positioned within the lumen 33  
20                  of needle 30 as shown in Figure 2. The location of the  
lesion within the body, such as non-palpable lesions found in  
the breast or organs deep within the body, is determined  
radiologically or ultrasonically in a non-invasive procedure.  
In order to biopsy the lesion or remove it, the surgeon must  
25                  have an accurate location of the lesion prior to performing  
the surgical procedure to minimize damage to tissue. The  
accuracy of the location of the marker will obviate any need  
for additional incisions, as well as avoid unnecessary tissue  
removal, which benefits the patient both physically and  
30                  cosmetically. The use of a marking device such as in the  
present invention is illustrated in Figures 4, 5 and 6.

1        As seen in Figure 4, the needle and marker assembly  
50 is inserted into the body through the skin surface 52  
until cutting tip 34 of cannula 32 is positioned proximate a  
lesion or tumor 54. Marking device 10 is positioned within  
5 needle 30 such that sharpened tip 16 of helical marking wire  
14 is positioned adjacent to cutting tip 34 of needle 30.  
The length of needle 30, as well as the length of shaft 12  
and distance "d" between marking wire 14 and guide wire 18 is  
determined by the depth or distance lesion 54 is from the  
10 surface of the skin 52. Distance "d" is determined such that  
when marking device 10 is within the lumen 33 of needle 30,  
forward end 19 of helical guide wire 18 engages and rests  
against guide bar 42, resulting in sharpened tip 16 being  
adjacent to cutting tip 34.

15        Turning now to Figure 5, after cutting tip 34 is  
positioned proximate to lesion 54, marking device 10 is  
rotated about shaft 12 to advance helical marking wire 14  
into lesion 54. Sharpened tip 16 enters lesion 54 and the  
20 rotation about shaft 12 further advances marking wire 14 into  
the lesion to firmly anchor it in place. The depth to which  
helical marking wire 14 enters lesion 54 is determined by the  
distance helical guide wire 18 travels through hole 46 into  
cannula 32. As shaft 12 is rotated, guide bar 42 of wire  
25 guide 40 engages the shaft and helix 18 at end 19 of helix 18  
and guides shaft 12 while allowing helical guide wire 18 to  
rotate into hole 46 in a screw-like fashion. Guide bar 42 is  
positioned between the individual coils of helical guide wire  
18 to prevent slipping or pulling on the shaft. Wire guide  
30 40 may be secured in hole 47 or may be pivotably secured so  
that guide bar 42 may rotated away from shaft 12 to disengage  
guide bar 42 from helix 18.

1        When helical marking wire 14 is embedded and  
anchored in lesion 54, that is when the end 23 of shaft 12 is  
proximate to the lesion 54, the rotation is ceased. This is  
best seen in Figure 6. The surgeon may determine when marking  
5 wire 14 is in its desired position with respect to lesion 54  
when guide wire 18 completely disappears into knob 36 past  
guide bar 42. The trailing end 21 of guide wire 18 is the  
same distance from the end 23 of shaft 20 as the distance  
between forward end 19 of guide wire 18 and sharpened tip 16  
10 of marking wire 14. When the surgeon determines that the  
marking wire 14 is in proper position, such as when it is  
completely embedded in the lesion, as evidenced by trailing  
end 21 of helix 18 turning into knob 36, the surgeon may then  
remove needle 30 from the body leaving marking device 10  
15 firmly embedded in the lesion. Alternatively, when it is  
determined that the helix 14 is in a desired position with  
respect to lesion 54 without helix 18 being completely within  
cannula 32, such as when a lesion is located proximate the  
20 chest wall as determined by ultrasonic imaging, wire guide 40  
may be pivoted to rotate guide bar 42 away from helix 18 to  
allow for removal of needle 30 without disturbing the  
position of helix 14. Marking device 10 remains firmly  
anchored due to the concentric nature of the coils of marking  
25 wire 14 and eliminates the possibility of inadvertent  
dislodgement due to relaxation of the tissues of the breast  
upon discontinuing the compression placed on the breast  
during the procedure.

30        Figure 7 illustrates an alternate embodiment of the  
present invention showing marking device 10a, in which helix  
14a and helix 18a are integrally wound as part of shaft 12a.  
Figure 7 is identical to Figure 1 in operation and function  
except that additional helical wires are not needed, since

1 marking device 10a is of unitary construction in that shaft 12a and helixes 14a and 18a are constructed as a single unit. In a further embodiment, helix 14 and helix 18 may be joined so that the entire shaft 12 is in a helical coil.

5 In a further embodiment, cannula 32 may be provided with a notched portion 60, and knob 36 may be eliminated, as seen in Figure 8. In this case, notch 60 engages helix 18, or alternately helix 14, dependent upon location of notch 60. Notch 60 will then guide marking device 10 in the same manner 10 as wire guide 40 and guide bar 42.

While the invention has been particularly shown and described with reference to the preferred embodiments, it will be understood by those skilled in the art the various changes in form and detail may be made therein without 15 departing from the spirit and scope of the invention. Accordingly, modifications and/or changes such as removing guide wire 18 or providing a longer or shorter marking wire, as well as increasing or decreasing the pitch of the coils as related to the number turns per centimeter, may be provided 20 as desired, and are considered to be within the scope of the invention.

25

30

35

-18-

1 WHAT IS CLAIMED IS:

1. A needle assembly for localization of lesions within the body, including a needle cannula, said cannula having a cutting edge at a first end; and a 5 marking device positioned within said cannula and including a shaft, said marking device being characterized by a wire (14; 14a) helically wound at one end (23; 23a) of said shaft (12; 12a) and extending beyond said end a predetermined distance in a helical coil, and having a 10 sharpened tip (16; 16a), said marking device (10) being axially slideable and rotatable within said cannula (32).

2. A needle assembly according to Claim 1, characterized in that said wire (14) is wound about and secured to said shaft (12).

15 3. A needle assembly according to Claim 1 or 2, characterized in that said cannula (32) and said marking device (10) are constructed of biocompatible material, such as stainless steel or a metal alloy.

4. A needle assembly according to any of Claims 20 1 to 3, characterized in that said helical coil of said wire (14; 14a) has a constant diameter along its length.

5. A needle assembly according to any of Claims 1 to 4, characterized in that said cannula (32) has a lumen (33); at least one notched portion (60) on said 25 cannula; said marking device (10) engaging said at least one notched portion, such that advancement of said marking

-19-

1 device is assisted by said helical wire (14; 14a) at one end of said marking device rotatingly contacting said at least one notched portion.

6. A needle assembly according to any of Claims 5 1 to 5, characterized in that said cannula (32) has a lumen (33), a cutting edge (34) at a first end of said cannula, and a gripping knob (36) secured at a second end of said cannula, said knob having a first hole (46) formed therethrough in alignment with said lumen (33), and a 10 second hole (47) formed therethrough offset from said first hole and having a wire guide (40) passing through secured within said second hole in a direction parallel to said cannula, said wire being bent at a right angle to partially cover said first hole; said marking device (10) 15 further including a second helical wire (18) coiled about said shaft (12) and secured thereto a distance from said first helical wire (12) towards a second end of said shaft; said second helical wire of said shaft engaging said wire guide of said knob (36), such that the 20 advancement of said shaft is assisted by said second helical wire (18) rotatingly contacting said wire guide (40).

7. A needle assembly according to Claim 6, characterized in that said first and second helical wires 25 (14, 18) of said marking device (10) are secured to said shaft (12) by soldering.

-20-

1           8. A needle assembly according to Claim 6 or 7, characterized in that said first helical wire (14) extends past said shaft end (23) a predetermined distance which is equal to the length of said second helical wire (18).

5           9. A needle assembly according to any of Claims 6 to 8, characterized in that said second helical wire (18) is positioned a predetermined distance from said first helical wire (14), such that when an end of said second helical wire closest to said first helical wire 10 engages said wire guide (40) of said knob (36), said sharpened tip (16) of said first helical wire is positioned coaxial and adjacent to said cutting edge of said cannula.

10. A needle assembly according to Claim 8, 15 characterized in that an end of said second helical wire (18) remote from said first helical wire (14) is positioned at a distance such that when said second end is rotated past said wire guide (40) into said cannula (32), said first end of said shaft (12) is positioned coaxial 20 and adjacent to said cutting edge (34) of said cannula (32).

11. A needle assembly according to any of Claims 6 to 10, characterized in that said first and second helical wires (14, 18) have a constant diameter along 25 their entire lengths.

-21-

1           12. A needle assembly according to Claim 11,  
characterized in that said first and second helical wires  
(14, 18) have a diameter substantially equal to each other  
and less than the diameter of said shaft (12) of said wire  
5 marker (10).

13. A needle assembly according to Claim 12,  
characterized in that said first and second helical wires  
(14, 18) have a diameter of approximately 0.02 cm and said  
shaft (12) has a diameter of approximately 0.04 cm inches.

10           14. A needle assembly according to any of Claims  
8 to 13, characterized in that said predetermined distance  
of said first helical wire (14) extends past said shaft  
end and the length of said second helical wire (18) is  
between 0.5 and 2.0 cm.

15           15. A needle assembly according to Claim 14,  
characterized in that said predetermined distance is 1 cm.

16. A needle assembly according to any of Claims  
6 to 15, characterized in that said first and second  
helical wires (14, 18) are wound about said shaft (12) an  
20 identical number of turns per centimeter.

17. A marking device for use in combination with  
a needle assembly for marking lesions within the body,  
according to any of the preceding claims, characterized by  
a shaft (12); a first helically coiled wire (14) secured  
25 to and wound about a first end of said shaft, said first  
wire extending concentrically outwardly from said first

-22-

- 1 end and away from said shaft a predetermined length and terminating in a sharpened tip (16); and a second helically coiled wire (18) secured to and wound about said shaft a distance from said first helically coiled wire,
- 5 said second wire having a length equal to said predetermined length that said first wire extends from said shaft; wherein said first and second helically coiled wires are wound an equal number of turns of between 6 and 15 turns per centimeter.
- 10 18. A method for marking non-palpable lesions within the body, characterized by puncturing the skin to enter the body with a marking needle assembly, said needle assembly including a cannula having a lumen, a cutting edge at one end of said cannula and a gripping means on
- 15 said cannula, said needle assembly further including a marking device positioned within said lumen, said marking device having a helical wire helically wound at one end a predetermined distance in a helical coil, and having a sharpened tip; aid marking device being axially slidable
- 20 and rotatable within said cannula; tracking said needle assembly inside said body; advancing said needle assembly to a point within proximity to a lesion within said body; rotating said marking device within said cannula to advance said marking device; determining the distance said
- 25 marking device travels by the distance said marking device is advanced into said cannula; ceasing rotation of said

-23-

1 marking device when said marking device is positioned  
within a determined proximal distance of said lesion; and  
removing said cannula from said body; wherein said marking  
device remains in position with respect to said lesion to  
5 mark said lesion for subsequent medical procedures.

19. A method according to Claim 18,  
characterized in that said gripping means includes a  
gripping knob having a first hole formed therethrough  
aligned with said lumen and a second hole formed  
10 therethrough offset and parallel to said first hole for  
receiving a wire guide, said wire guide bent at an angle  
perpendicular to said second hole and covering a part of  
said first hole, said needle assembly further including a  
marking device positioned within said lumen, said marking  
15 device having a shaft and at least two helically wound  
wires concentrically coiled about and secured to said  
shaft and spaced from each other a predetermined distance,  
a first helical wire secured at an end of said shaft and  
concentrically extending outwardly a predetermined length  
20 from said shaft and terminating in a sharpened end, and a  
second helical wire coiled about said shaft having an  
equal number of turns per centimeter as said first helical  
wire, a first end of said second helical wire engaging  
said wire guide while said sharpened end of said first  
25 helical wire is adjacent to said cutting edge of said  
cannula;

-24-

1        said rotating of said marking device within the lumen of said cannula advancing said marking device such that said wire guide draws said marking device through said lumen by engaging said second helical wire;

5        determining the distance said first helical wire travels by the distance said second helical wire has travelled past said wire guide; ceasing rotation when said first helical wire marks said lesion; and removing said cannula from said body;

10        wherein said first helical wire remains in position with respect to said lesion to mark said lesion for subsequent medical procedures.

20.        A method according to Claim 19, characterized in that said rotation continues until said 15 first helical wire is embedded in said lesion and said second helical wire passes fully into said knob beyond said wire guide.

21.        A marking device for implementing the method according to any of Claims 19 or 20.

20

25

1 / 3

FIG. 1

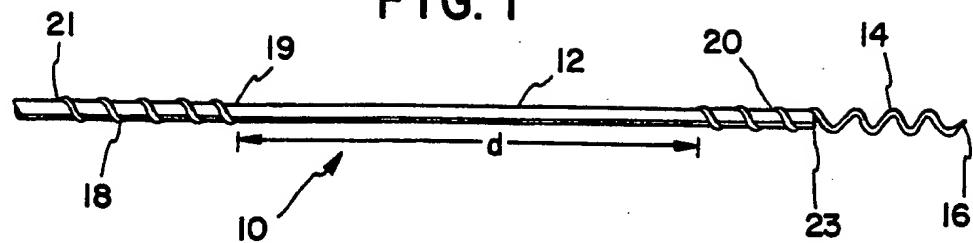


FIG. 2

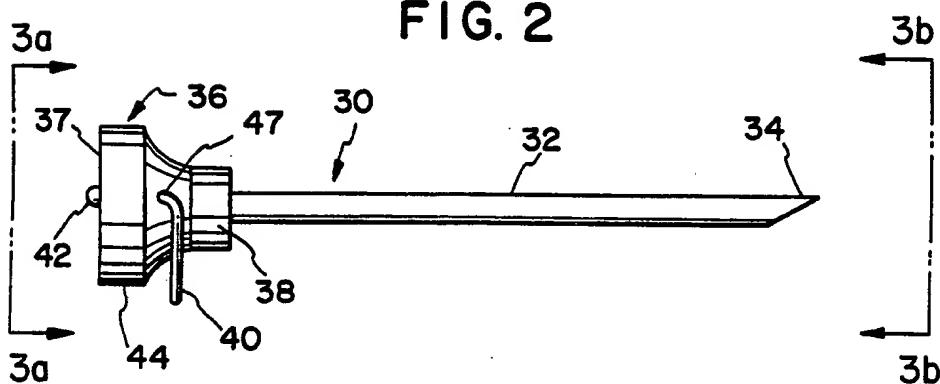


FIG. 3b

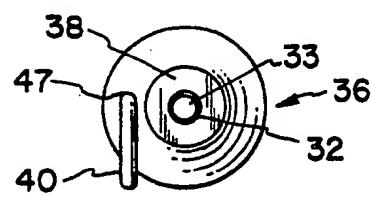
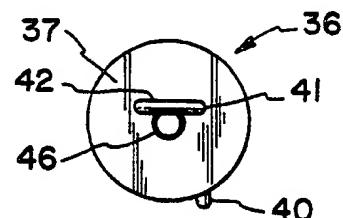


FIG. 3a



BEST AVAILABLE COPY

SUBSTITUTE SHEET

2 / 3

FIG. 4

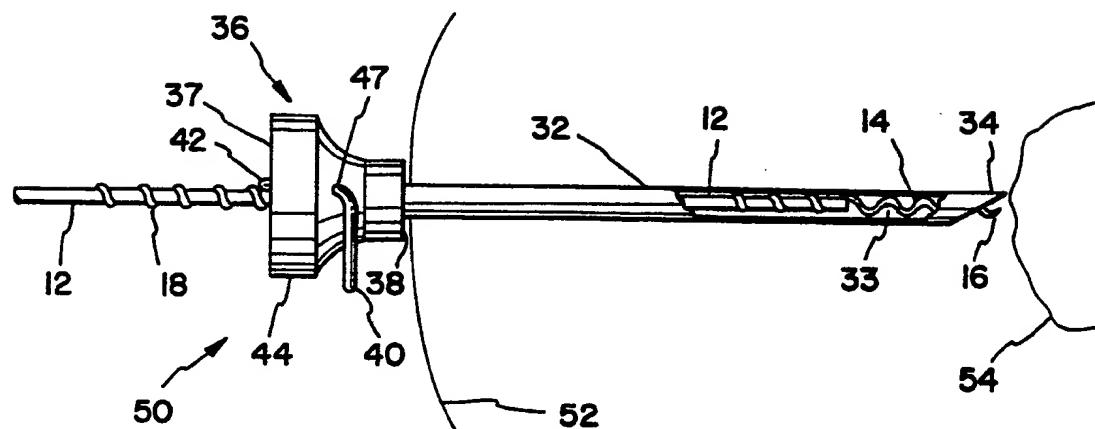
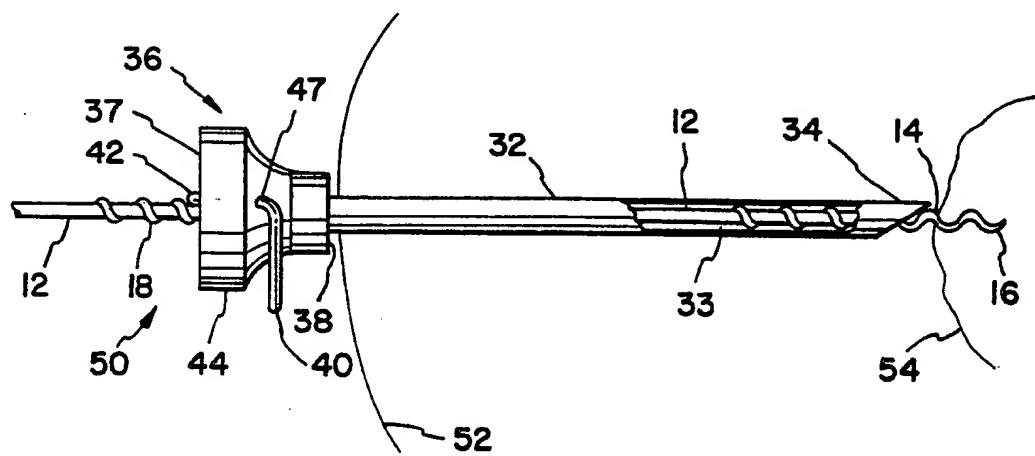


FIG. 5



BEST AVAILABLE COPY

SUBSTITUTE SHEET

3 / 3

FIG. 6

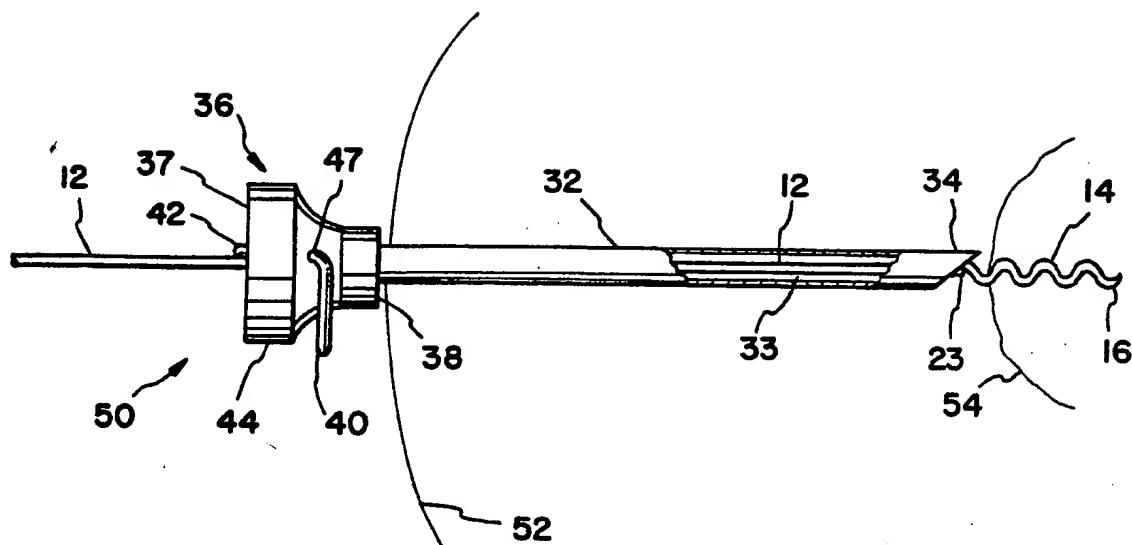


FIG. 7

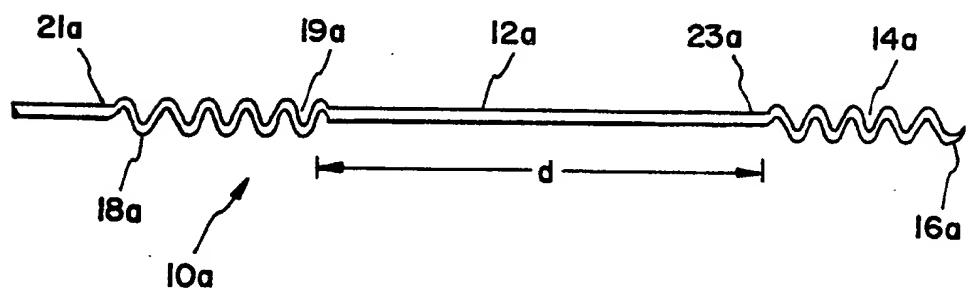
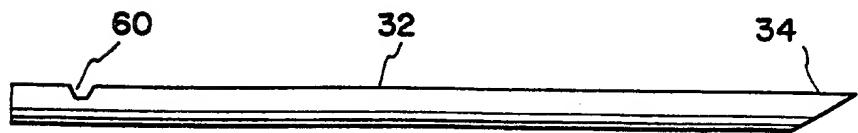


FIG. 8



BEST AVAILABLE COPY

SUBSTITUTE SHEET

# INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/03244

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>3</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC (5): A61B 10/00		
U.S.CI.: 128/749		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>4</sup>		
Classification System	Classification Symbols	
U.S.CI.	128/658, 753, 630, 749, 754 73/426-428 604/164 606/221-225, 104, 96, 180 81/3.45	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>5</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>14</sup>		
Category <sup>6</sup>	Citation of Document, <sup>10</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No. <sup>18</sup>
Y	US, A, 2,850,007 (LINGLEY) 02 September 1958 col. 2 lines 18-41	1, 3-6, 8-12, 14-16, 18
Y	US, A, 4,616,656 (NICHOLSON) 14 October 1986 col. 3 line 6	3
Y	Radiology 117, November, 1975 Nordenstrom page 474, line 5	3, 13
Y	US, A, 4,548,206 (OSBORNE) 22 October 1985 col. 3 lines 37-44	2, 7, 17, 21
Y	US, A, 4,658,678 (PRACHT) 21 April 1987 col. 3, lines 37-59	5
Y	US, A, 3,683,891 (ESKRIDGE et al.) 15 August 1972 col. 2, 3 lines 63 +	17, 21
* Special categories of cited documents: <sup>15</sup>		
"A" document defining the general state of the art which is not considered to be of particular relevance		
"E" earlier document but published on or after the international filing date		
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)		
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention		
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step		
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art		
"a" document member of the same patent family		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search <sup>9</sup>	Date of Mailing of this International Search Report <sup>9</sup>	
09 August 1990	02 OCT 1990	
International Searching Authority <sup>1</sup>	Signature of Authorized Officer: NGOC-HO INTERNATIONAL DIVISION for Robin R. Longo <i>Robin R. Longo</i>	
ISA/US		